AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Withdrawn) A freeze-dried composition for transpulmonary administration prepared by freeze-drying a composition liquid containing ingredients in a non-dissolved form which has the following properties (i) to (iii):

(i) a non-powder cake-like form,

(ii) a disintegration index of 0.05 or more, and

(iii) becoming fine particles having a mean particle diameter (mass median aerodynamic diameter) of 10 microns or less or a fine particle fraction of 10% or more upon receipt of an air impact having an air speed of at least 1m/sec and an air flow rate of at least 17 ml/sec.

2. (Withdrawn) The freeze-dried composition according to Claim 1, wherein a high-molecular-weight drug is contained as an active ingredient.

3. (Withdrawn) A method of manufacturing a dry powdered preparation for transpulmonary administration, comprising:

introducing air into a vessel to apply to a freeze-dried composition an air impact having an air speed of at least 1m/sec and an air flow rate of at least 17 ml/sec using a device capable of applying said air impact to the freeze-dried composition in the vessel,

thereby making said freeze-dried composition into fine particles having a mean particle diameter (mass median aerodynamic diameter) of 10 microns or less or a fine particle fraction of 10% or more;

the freeze-dried composition prepared by freeze-drying a composition liquid containing ingredients in a non-dissolved form and having the following properties:

(i) a non-powder cake-like form,

(ii) a disintegration index of 0.05 or more, and

(iii) becoming fine particles having a mean particle diameter of 10 microns or less or a fine particle fraction of 10% or more upon receipt of the air impact.

4. (Withdrawn) The method of manufacturing a dry powdered preparation for transpulmonary administration according to Claim 3, wherein the freeze-dried composition contains a high-molecular-weight drug as an active ingredient.

5. (Withdrawn) The method of manufacturing a dry powdered preparation for transpulmonary administration according to Claim 3 comprising pulverizing a freeze-dried composition into fine particles using a dry powder inhaler described under item (A) or (B) as a device:

(A) a dry powder inhaler for transpulmonary administration, being a device used for making a freeze-dried composition that has been housed in non-powder form in a vessel into fine particles, and administering the resulting fine particles to a user by inhalation,

comprising a needle part having an air jet flow path, a needle part having a discharge flow path, air pressure-feeding member for feeding air into the air jet flow path of said needle part, and an inhalation port that communicates with the discharge flow path of said needle part,

and characterized by being constituted such that a stopper that seals up said vessel is pierced by said needle parts, thus communicating the air jet flow path and the discharge flow path with the inside of said vessel, and air is jetted into said vessel through said air jet flow path using said air pressure-feeding member, thus pulverizing

said freeze-dried composition into fine particles by the impact of the jetted air, and discharging the fine particles obtained from the inhalation port via said discharge flow path, or

(B) a dry powder inhaler for transpulmonary administration, being a device used for making a freeze-dried composition that has been housed in non-powder form in a vessel into fine particles, and administering the resulting fine particles to a user by inhalation,

comprising a needle part having a suction flow path, a needle part having an air introduction flow path, and an inhalation port that communicates with said suction flow path,

and characterized by being constituted such that, in a state in which a stopper sealing up said vessel has been pierced by said needle parts, through the inhalation pressure of the user, air in said vessel is inhaled from said inhalation port, and at the same time outside air flows into said vessel, at a negative pressure, through said air introduction flow path, and as a result said freeze-dried composition is pulverized into fine particles by the impact of the air flowing in, and the fine particles obtained are discharged from the inhalation port through said suction flow path.

6. (Currently Amended) A dry powder inhalation system for transpulmonary administration, ~~using a combination of~~ comprising:

(1) a vessel housing a freeze-dried composition prepared by freeze-drying a liquid composition ~~liquid~~ containing ingredients in a non-dissolved form, and has:

in a non-dissolved form, and has:

(i) a non-powder ~~cake-like~~ form;

(ii) a disintegration index of 0.05 or more, and

(iii) a property of becoming fine particles having a ~~mean particle diameter (~~mass median aerodynamic diameter~~)~~ of 10 microns or less or a fine particle fraction of 10% or more upon receiving an air impact having an air speed of at least 1 m/sec and an air flow rate of at least 17 ml/sec; and

(2) a device comprising a member capable of applying said air impact to the freeze-dried composition in said vessel, and a member for discharging the ~~powder-form~~ freeze-dried composition that has been made into fine particles.

7. (Original) The dry powder inhalation system for transpulmonary administration according to Claim 6, wherein the vessel and the device are used in combination at the time of inhalation.

8. (Currently Amended) The dry powder inhalation system for transpulmonary administration according to Claim 6, wherein the freeze-dried composition contains a ~~high-molecular-weight~~ drug as an active ingredient.

9. (Original) The dry powder inhalation system for transpulmonary administration according to Claim 6, wherein the device is:

A) a dry powder inhaler for transpulmonary administration, being a device used for making a freeze-dried composition that has been housed in non-powder form in a vessel into fine particles and administering the resulting fine particles to a user by inhalation,

comprising a needle part having an air jet flow path, a needle part having a discharge flow path, air pressure-feeding member for feeding air into the air jet flow path

of said needle part, and an inhalation port that communicates with the discharge flow path of said needle part,

and characterized by being constituted such that a stopper that seals up said vessel is pierced by said needle parts, thus communicating the air jet flow path and the discharge flow path with the inside of said vessel, and air is jetted into said vessel through said air jet flow path using said air pressure-feeding member, thus pulverizing said freeze-dried composition into fine particles by the impact of the jetted air, and discharging the fine particles obtained from the inhalation port via said discharge flow path, or

B) a dry powder inhaler for transpulmonary administration, being a device used for making a freeze-dried composition that has been housed in non-powder form in a vessel into fine particles, and administering the resulting fine particles to a user by inhalation,

comprising a needle part having a suction flow path, a needle part having an air introduction flow path, and an inhalation port that communicates with said suction flow path,

and characterized by being constituted such that, in a state in which a stopper sealing up said vessel has been pierced by said needle parts, through the inhalation pressure of the user, air in said vessel is inhaled from said inhalation port, and at the same time outside air flows into said vessel, at a negative pressure, through said air introduction flow path, and as a result said freeze-dried composition is pulverized into fine particles by the impact of the air flowing in, and the fine particles obtained are discharged from the inhalation port through said suction flow path.

10. (Withdrawn) A transpulmonary administration method comprising:

making a freeze-dried composition into fine particles having a mean particle diameter of 10 microns or less or a fine particle fraction of 10% or more by applying an air impact having an air speed of at least 1 m/sec and an air flow rate of at least 17 ml/sec to the freeze-dried composition at the time of use, and

administering the resulting fine particle powder to a user by inhalation;

the freeze-dried composition having prepared by freeze-drying a composition liquid containing ingredients in a non-dissolved form and having the following properties:

(i) a non-powder cake-like form,

(ii) a disintegration index of 0.05 or more, and

(iii) becoming fine particles having a mean particle diameter of 10 microns or less or a fine particle fraction of 10% or more upon receipt of the air impact.

11. (Withdrawn) The transpulmonary administration method according to Claim 10, wherein the freeze-dried composition is housed in a vessel, and the fine particle powder are prepared using a device comprising a member capable of applying the air impact to the freeze-dried composition in the vessel and a member for discharging the resulting fine particle powder-form freeze-dried composition out of the vessel.

12. (Withdrawn) The transpulmonary administration method according to Claim 10, wherein the freeze-dried composition contains a high-molecular-weight drug as an active ingredient.

13. (Withdrawn) The transpulmonary administration method according to Claim 11, using a dry powder inhaler described under item (A) or (B) as the device:

(A) a dry powder inhaler for transpulmonary administration, being a device used for making a freeze-dried composition that has been housed in non-powder form in a vessel into fine particles, and administering the resulting fine particles to a user by inhalation,

comprising a needle part having an air jet flow path, a needle part having a discharge flow path, air pressure-feeding member for feeding air into the air jet flow path of said needle part, and an inhalation port that communicates with the discharge flow path of said needle part,

and characterized by being constituted such that a stopper that seals up said vessel is pierced by said needle parts, thus communicating the air jet flow path and the discharge flow path with the inside of said vessel, and air is jetted into said vessel through said air jet flow path using said air pressure-feeding member, thus pulverizing said freeze-dried composition into fine particles by the impact of the jetted air, and discharging the fine particles obtained from the inhalation port via said discharge flow path, or

(B) a dry powder inhaler for transpulmonary administration, being a device used for making a freeze-dried composition that has been housed in non-powder form in a vessel into fine particles, and administering the resulting fine particles to a user by inhalation,

comprising a needle part having a suction flow path, a needle part having an air introduction flow path, and an inhalation port that communicates with said suction flow path,

and characterized by being constituted such that, in a state in which a stopper sealing up said vessel has been pierced by said needle parts, through the inhalation pressure of the user, air in said vessel is inhaled from said inhalation port, and at the same time outside air flows into said vessel, at a negative pressure, through said air introduction flow path, and as a result said freeze-dried composition is pulverized into fine particles by the impact of the air flowing in, and the fine particles obtained are discharged from the inhalation port through said suction flow path.

14. (Withdrawn) Use of a freeze-dried composition for transpulmonary administration by inhalation,

the freeze-dried composition prepared by freeze-drying a composition liquid containing ingredients in a non-dissolved form and having the following properties:

(i) a non-powder cake-like form,

(ii) a disintegration index of 0.05 or more, and

(iii) becoming fine particles having a mean particle diameter of 10 microns or less or a fine particle fraction of 10% or more upon receipt of an air impact having an air speed of at least 1 m/sec and an air flow rate of at least 17 ml/sec, and being used by forming into fine particles having said mean particle diameter or said fine particle fraction.

15. (Withdrawn) The use of a freeze-dried composition for transpulmonary administration according to Claim 14, wherein the freeze-dried composition is housed in a vessel, and the fine particles are prepared using a device comprising a member capable of applying the air impact to the freeze-dried composition in the vessel and a

member for discharging the resulting fine particle powder-form freeze-dried composition out of the vessel.

16. (Withdrawn) The use of a freeze-dried composition for transpulmonary administration according to Claim 14, wherein the freeze-dried composition contains a high-molecular-weight drug as an active ingredient.

17. (Withdrawn) Use of a freeze-dried composition for manufacture of a dry powdered preparation for transpulmonary administration by inhalation,

the freeze-dried composition having the following properties:

(i) being prepared by freeze drying a composition liquid containing ingredients in the non-dissolved form,

(ii) a non-powder cake-like form,

(iii) a disintegration index of 0.05 or more, and

(iv) becoming fine particles having a mean particle diameter of 10 microns or less or a fine particle fraction of 10% or more upon receipt of an air impact having an air speed of at least 1 m/sec and an air flow rate of at least 17 ml/sec,

and being used by forming into fine particles having said mean particle diameter or said fine particle fraction at the time of use.

18. (Withdrawn) The use of a freeze-dried composition for manufacture of a dry powdered preparation for transpulmonary administration by inhalation according to Claim 17, wherein the freeze-dried composition contains a high-molecular-weight drug as an active ingredient.

19. (Withdrawn) The use of a freeze-dried composition for manufacture of a dry powdered preparation for transpulmonary administration according to Claim 17, wherein

the freeze-dried composition is housed in a vessel, and the fine particles are prepared by using a device comprising a member for applying a prescribed air impact to the freeze-dried composition housed in the vessel and a member for discharging the resulting fine particle powder form freeze-dried composition out of the vessel.

20. (Withdrawn) Use of a composition liquid containing ingredients in the non-dissolved form for manufacturing of a freeze-dried composition having the following properties, which is used for manufacture of dry powdered preparation for transpulmonary administration:

(i) a non-powder cake-like form,

(ii) a disintegration index of 0.05 or more, and

(iii) becoming fine particles having a mean particle diameter of 10 microns or less or a fine particle fraction of 10% or more upon receipt of an air impact having an air speed of at least 1 m/sec and an air flow rate of at least 17 ml/sec, and being used by forming into fine particles having said mean particle diameter or said fine particle fraction at the time of use.

21. (Withdrawn) The use of a composition liquid containing ingredients in the non-dissolved form according to Claim 20, wherein the freeze-dried composition contains a high-molecular-weight drug as an active ingredient.

22. (Withdrawn) The use of a composition liquid containing ingredients in the non-dissolved form according to Claim 20, wherein the freeze-dried composition is housed in a vessel, and the fine particles are prepared by using a device comprising a member for applying a prescribed air impact to the freeze-dried composition housed in

the vessel and a member for discharging the resulting fine particle powder form freeze-dried composition out of the vessel.